

4B1 amplifying the nucleic acids. —

CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Assistant Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

The drawings were objected to for the reasons indicated on Form PTO-948. In response, Applicants respectfully request that this issue be held in abeyance until allowable subject matter is indicated. See, 37 CFR § 1.111(b) (“[A] request may be made that objections or requirements as to form not necessary to further consideration of the claims be held in abeyance until allowable subject matter is indicated.”) Although the Examiner required a proposed drawing

change be submitted, Applicants submit that this is not possible without actually undertaking the cost and effort of making formal drawings, and Applicants respectfully request that this be held in abeyance until it is clear that the application may be allowed.

The specification was objected to for a typographical error on page 23, at lines 7-8. In response, Applicants have corrected this typographical error.

Claims 9-12 were rejected under 35 USC § 101 as being improper method claims. In response, Applicants point out that claims 9-12 have been canceled, and replaced by claims 20-23 and 25-28, which are in the proper method format.

For the Examiner's information, Applicants point out that the new claims correspond to the original claims as follows:

<u>New Claims</u>	<u>Original Claims</u>
13-15	1-3, respectively
16	5
17	New; supported by page 18, lines 19-20
18-19	6-7, respectively
20-23	9-12, respectively
24	8
25-28	9-12, respectively

No new matter has been introduced.

Claims 1-8 were rejected under 35 USC § 112, first paragraph, as being broader than the enabling disclosure.

Claims 1-8 were separately rejected under 35 USC § 112, first paragraph, as being based on a disclosure which is not enabling.

In response to *both* lack of enablement rejections, Applicants would remind the Examiner that the allegations in the specification must be accepted as true, and enablement found, unless the Examiner provides evidence or sound scientific reasoning that tends to cast doubt on the allegations in the specification. In re Marzocchi et al., 169 USPQ 367, 369 (CCPA 1971). Although the Examiner has provided reasons why he believes the specification is lacking an adequate enabling disclosure, Applicants do not believe that these reasons are sound in the context of the present invention. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw these lack of enablement rejections.

As should be clear from the discussion beginning in the last paragraph on page 5 of the specification and continuing over to the third paragraph on page 7, the present invention incorporates a *physical* isolation and concentration of macromolecules, which can then be subjected to any desired analysis. The inventive method involves placing the molecules in a channel, applying a pressure and/or voltage difference across the channel so that the macromolecules migrate to one end or the other, and placing a membrane in the path of such

migration so that the macromolecules collect in front of or in the membrane, but do not pass through. For such purpose, it is possible to employ membranes which operate on the size exclusion principle, so that other components of the sample pass through the membrane, but the macromolecules do not, and, thus, are collected, and, thereby, concentrated, in front of or in the membrane. See, the specification at page 6, lines 20-25.

It should be clear from the foregoing, that the present invention does not operate on unpredictable biological factors, but, rather, on more predictable physical parameters. Consequently, the amount of disclosure required to satisfy the enablement requirement here is not nearly the same as would be required to satisfy the enablement requirement in cases such as Genentech v. Novo Nordisk A/S, 42 USPQ2d 1001, as cited by the Examiner.

The Examiner accepts the enablement for isolating nucleic acids, but not for other macromolecules, such as viruses, proteins, bacteria or fungi. In this regard, the Examiner focuses on the examples at pages 21-24 of the specification, which describe the isolation of nucleic acids, and the apparent lack of examples for other macromolecules, such as viruses, proteins, bacteria or fungi. However, the Examiner ignores the detailed description beginning at page 12, line 15, continuing over to page 18, line 8, wherein details are given for applying the inventive method to viruses, protein and bacteria, and, also, the specific example at page 24, line 30, continuing over to page 25, line 11, showing the application of the inventive method to herpes simplex viruses. Clearly, the specification does, in fact, enable persons skilled in the art to use the inventive

method with macromolecules other than nucleic acids.

Moreover, again considering the physical nature of the present invention, the Examiner has not made a case why the choice of macromolecule would be expected to be critical. Since the inventive method is physical in nature, and not biological in nature, persons skilled in the art would be reasonable to expect that the inventive method is applicable to any macromolecule, and that the examples with nucleic acids are just that – exemplary.

In similar fashion, the Examiner accepts the enablement for PCTE membranes, but apparently not any other. Again, the Examiner ignores the teaching at page 6, lines 25-31, that the membranes may be selected from a wide variety of types of membranes. Again, given the physical nature of the invention, Applicants submit that the Examiner has not made out a sound case that the choice of membrane would have been expected to be critical. Quite the contrary, given the physical nature of the invention, and the stated goal of concentrating the macromolecules in front of or in the membrane, Applicants submit that persons skilled in the art would reasonably expect any of a number of different membranes would be useful.

The Examiner also accepts the enablement for a single capillary device, but not other devices. This is in spite of the fact that Figures 7 and 8 depict a multiple capillary device, and the Examiner does not indicate what would be the technical obstacles in going from such device to other devices with multiple capillaries.

Respectfully, the enablement here is more than adequate for the coverage sought, and given the nature of the invention. This is particularly true in view of the fact that the Examiner has not cited a single prior art reference against the claims. As stated by the court in In re Hogan et al., 194 USPQ 527, 537 (CCPA 1977): "The record reflects no citation of prior art disclosing [applicant's invention], which may suggest that appellants at least broke new ground in a broad sense. * * * As pioneers, if such they be, they would deserve *broad claims to the broad concept.*"

In view of the foregoing, Applicants submit that the Examiner would be fully justified to reconsider and withdraw both lack of enablement rejections. An early notice that these rejections have been reconsidered and withdrawn is earnestly solicited.

Claims 6 and 9-12 were rejected under 35 USC § 112, second paragraph, as being indefinite. In response, Applicants have canceled the rejected claims and replaced them by new claims which Applicants believe are free of the Examiner's concerns. Thus, new claim 18, which replaces claim 6, specifies that the "side by side" arrangement applies if the device contains multiple capillaries. Also, new claim 24, which replaces claim 8, does not use the term "shallow."

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

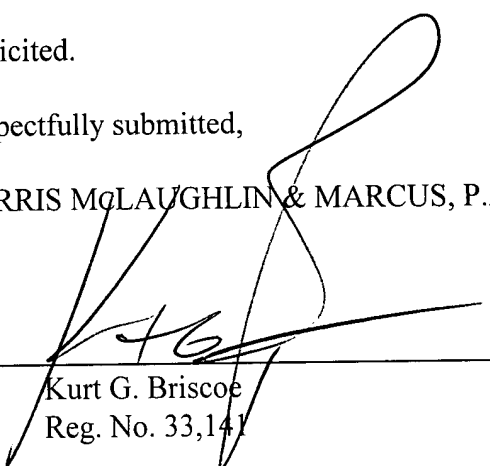
Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (914) 332-1700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

NORRIS McLAUGHLIN & MARCUS, P.A.

By


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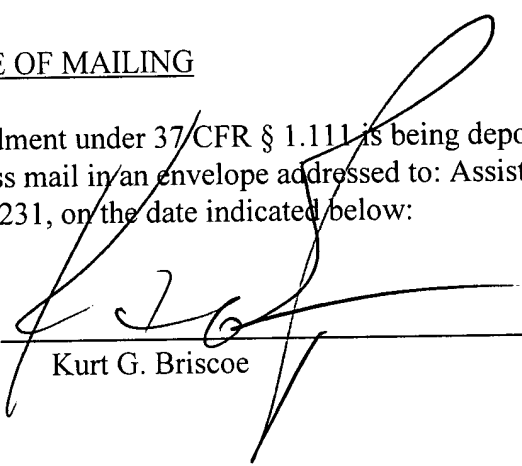
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CERTIFICATE OF MAILING

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date indicated below:

Date: July 21, 2000

By


Kurt G. Briscoe